

REMARKS

Claims 1-3, 5, 6, 12-14, 16 and 18 are pending in this application. Claim 1 is amended herein. Upon entry of this amendment, claims 1-3, 5, 6, 12-14, 16 and 18 will be pending. Entry of this amendment and reconsideration of the rejections are respectfully requested.

No new matter has been introduced by this Amendment. The amendment to claim 1 corrects the term “medical device body” to –stent—, for proper antecedent basis.

Claims 1-3, 5-7, 12-14, 16 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berns (US 5,503,687) in view of Takemura et al. (US 4,059,440) and further in view of Jalisi et al. (US 6,508,832). (Office Action paragraph no. 3)

The present invention relates to the method for producing a stent for living soft tissue, and claim 1 recites the steps of:

a melting step of producing a ferritic stainless steel tube substantially free of Ni by melting method,

a working step of working said ferritic stainless steel tube to have a repeating shape on the peripheral surface in expanded form to obtain the stent, and after the working step

a nitrogen absorption step of bringing said stent into contact with a gas containing nitrogen at a treatment temperature range of 800°C to 1500°C to make said ferritic stainless steel forming said stent absorb nitrogen to transform all of said ferritic stainless steel tube to austenite.

The present invention uses the ferritic stainless steel substantially free of Ni; hence it is possible to provide a delicate, complicated medical device for living soft tissue having superior workability (refer to [0011] and [0006] of the present application).

Also, in the present invention, the ferritic stainless steel is brought into contact with nitrogen gas after the working step; thus, it is possible to provide superior corrosion resistance while maintaining sufficiently superior physical properties and practical properties with superior performances and safety (see present claim 1 and refer to [0006] of the present application).

That is, the present invention comprises the working step using the material which can be worked easily and then forms the austenite having mechanical strength and the corrosion resistance (refer to [0008], [0009] of the present application). Furthermore, thereby the present invention can provide the stent for a living soft tissue having superior mechanical strength and corrosion resistance.

In regard to Jalisi et al., this reference describes a stent of virtually free of nickel. However, in column 5, lines 13 to 33, Jalisi et al. describes that BioDur 108 Alloy may be used as the material. Importantly, Jalisi et al. recites that BioDur 108 Alloy is a nickel-free austenitic stainless steel alloy and the alloy contains a high nitrogen content (0.97 wt%) to maintain its austenitic structure (column 5, lines 21 to 22), and furthermore, Jalisi et al. describes that BioDur 108 Alloy is non-magnetic and essentially free of ferrite phase (column 5, lines 33 to 34).

According to columns 5 to 8 of Jalisi et al., it appears that Jalisi et al. directly process BioDur 108 Alloy, which has high levels of strength by solid dissolving the nitrogen during the material production, into a stent form.

When plastic processing is performed on the austenite stainless steel in which nitrogen is solid dissolved in advance, it causes a stress induced martensitic transformation and the material itself will become extremely hard. Moreover, it is metallurgically obvious that the mechanical characteristics such as corrosion resistance, resilience, nonmagnetic property, etc., which are essential characteristics as a stent, will significantly deteriorated.

Therefore, as discussed above, **contrary** to the starting material of the present invention, the starting material of Jalisi et al. is austenitic stainless steel; hence, even though Jalisi et al. attain the stent expandable in outside diameter, Jalisi et al. fail to satisfy the limitations recited in present claim 1. That is, Jalisi et al. fail to satisfy a melting step of producing ferritic stainless steel tube substantially free of Ni by melting method,

a working step of working said ferritic stainless steel tube to have a repeating shape on the peripheral surface in expanded form to obtain the steal, and

a nitrogen absorption step of bringing said stent into contact with a gas containing nitrogen at a predetermined treatment temperature or more to make said ferritic stainless steel forming said stent absorb nitrogen to transform all of said ferritic stainless steel to austenite.

Note that the high nitrogen content (0.97 wt%) of Jalisi et al. indicates that nitrogen is originally contained in the starting material. Hence, it can be said that this high nitrogen content indicates that Jalisi et al. does not comprise the nitrogen absorption step.

In regard to Berns, this reference discloses a ferritic stainless steel having a surface of austenite phase. According to Figs. 3 to 5, the starting material of Berns contains Ni (austenitic duplex steel Cr Ni Mo N 22 5 3). That is, Berns fails to specify the nickel-free stainless steel which is recited in the present claim 1.

Also, Berns fails to specify to use a material that can be worked easily as the starting material (that is, to use the ferritic stainless steel as the starting material as recited in the present claim 1).

Further, since the austenite phase is formed on the surface layer in the invention of Berns, it is difficult to work into a medical device for the soft tissue having a complicated shape (for example, into a shape of the stent recited in Jalisi et al.).

Thus, it would be difficult to obtain the medical device for the living soft tissue having a complicated structure (such as the stent expandable in outside diameter as recited in the present invention, and as the stent recited in Jalisi et al.) by combining Jalisi et al. and Berns.

In regard to Takemura et al., the invention of Takemura et al. relates to corrosion-resistant ferritic stainless steel. In column 3, lines 49 to 51, it is described that: "In case of the ferritic stainless steel, however, the metallurgical principle of their addition in an austenitic stainless steel does not apply at all." Then in column 6, lines 1 to 4, it is described that: "The steel according to the present invention remain a ferrite single phase steel under any heat treatment condition due to its main components and high purity".

It is clear from the above description that Takemura et al. does not aim to form an austenite. Therefore, Takemura et al. would teach away from the invention of Berns and Jalisi, since Berns aims to form an austenite on the surface and Jalisi et al uses an austenite stainless steel as the material.

Furthermore, not only does Takemura et al. teach away from Berns and Jalisi et al., Takemura et al. also teaches away from the present invention since the present invention transforms the ferritic stainless steel into austenite (the present claim 1).

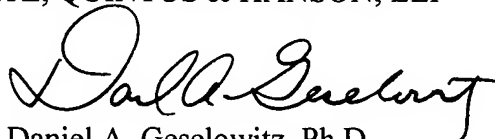
As discussed hereinabove, Jalisi et al., Berns, and Takemura et al. fail to simultaneously satisfy all the limitations recited in the present claim 1. Furthermore, there is no reasonable motivation to combine the teaching of Takemura et al with Berns and Jalisi et al., and Takemura et al. teaches away from the invention of Berns and Jalisi et al. Accordingly, the present claims are not obvious over Jalisi et al., Berns and Takemura et al., taken separately or in combination.

If, for any reason, it is felt that this application is not now in condition for allowance, the Examiner is requested to contact the applicants' undersigned agent at the telephone number indicated below to arrange for an interview to expedite the disposition of this case.

In the event that this paper is not timely filed, the applicants respectfully petition for an appropriate extension of time. Please charge any fees for such an extension of time and any other fees which may be due with respect to this paper, to Deposit Account No. 01-2340.

Respectfully submitted,

KRATZ, QUINTOS & HANSON, LLP



Daniel A. Geselowitz, Ph.D.
Agent for Applicants
Reg. No. 42,573

DAG/xl

Atty. Docket No. **050316**
4th Floor
1420 K Street, N.W.
Washington, D.C. 20005
(202) 659-2930



23850

PATENT & TRADEMARK OFFICE